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Glass Particulate Contamination From Medications Aspirated From Glass Ampules: Comparison of Filtered Versus Non-filtered Needles

A research project submitted in partial fulfillment of the requirements for the degree Master of Science at Virginia Commonwealth University

By

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Abstract

GLASS PARTICULATE CONTAMINATION FROM MEDICATIONS ASPIRATED FROM GLASS AMPULES: COMPARISON OF FILTERED VERSUS NON-FILTERED NEEDLES

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An investigation was undertaken to determine if there is a decrease in the number of glass particles aspirated from medications contained in glass ampules using filtered versus non-filtered needles of varying gauge. One hundred, 2 milliliter (ml) glass ampules were randomly assigned to one of four groups of needles: Group A, 18-gauge, non-filtered: Group B, 19-gauge, filtered; Group C, 20-gauge, non-filtered; and Group D, 25-gauge, non-filtered. Each ampule was opened by hand, aspirated through the specified needle into a ten milliliter syringe. The syringe was inverted several times to ensure mixing of glass particles in the solution. One and one half ml of the sample was expelled with the remaining 0.5 ml then examined under a light microscope with the glass particles observed counted.

The mean number of particles counted and standard deviation for each of the four groups of needles was calculated. Although results demonstrated that use of the 19-gauge filtered needle had the lowest number of glass particle contaminants (mean number of particles - 267.793), followed by the 20-gauge non-filtered (mean - 270.542), 18-gauge non-filtered (mean - 271.238), and 25-gauge non-filtered (mean - 279.769); analysis of variance (ANOVA) indicated no significant difference existed between the four groups. Thus, no significant difference existed in the number of glass particles counted following aspiration of medications from glass ampules using filtered needles compared to non-filtered needles, or when comparing non-filtered needles of varying sizes.

Chapter One

Introduction

There are several routes available for the administration of medications: oral (p.o.), nasal, topical, rectal, buccal, subcutaneous (S.Q.), intramuscular (I.M.), subarachnoid or intrathecal (S.A.B.), epidural and intravenous (I.V.). Patients undergoing surgery receive medications almost exclusively I.V. Many of the medications used by anesthesia providers are contained in single-dose glass ampules. These ampules are broken at a perforated neck and the medication can be aspirated out of the ampule by a needle and syringe. The required amount of medication is then injected through an established I.V. line to provide the desired effect to the patient. Studies have shown that the opening of glass ampules causes various sized glass particles to contaminate the medication. Katz, Borden, and Hirscher (1973) found glass particle contamination with the use of color-break ampules. Turco and Davis (1972) demonstrated that 2-ml ampules of Lasix

contained as many as several hundred glass particles after opening. Furgang (1974) noticed glass particles in single-dose glass ampules of local anesthetic solutions. These particulates were then aspirated with the medication out of the ampule and subsequently injected into the vascular system of the patient. Other research has studied the effects of foreign particle administration into the vascular system. Falchuk, Peterson and McNeil (1985) concluded that infusion-related phlebitis due to particulate contamination could lead to systemic complications. Brewer and Dunning (1947) reported that massive amounts of glass particles could produce organ damage.

Studies have also demonstrated that the use of filtered needles may reduce or eliminate contamination and subsequent vascular administration of glass particles. Sabon, Cheng, Stommel, and Hennen (1989) noted a significant reduction in glass particle contamination when either in-line filters or filtered needles were used. Carbone-Traber and Shanks (1986) demonstrated that glass particles were able to penetrate through filters and therefore did not provide any protection from glass particle contamination. Wall and George (1986) stated that the "contribution of particulate matter may be reduced by in-line filters, with pore sizes varying between 0.2 micrometer (um) and 0.5 um."

With this background of knowledge available, there remains a controversy in anesthesia practice - should filtered needles be used when aspirating medications from glass ampules? Some

hospitals require use of filtered needles when aspirating medications from glass ampules while other heath care facilities avoid purchasing them. This discrepancy in practice warrants further study to determine if filtered needles and non-filtered needles of varying sizes allow a similar amount of glass particle contamination to occur. If there is no difference between use of filtered or non-filtered needles or if there is a demonstrable difference, a standardization of practice may be warranted.

Statement of Purpose

The purpose of this study is to determine if there is a significant reduction in the number of glass particles obtained from drugs in glass ampules when using filtered needles compared with non-filtered needles of varying gauges.

Statement of Problem

Are there less glass particles obtained from opened glass ampules using filtered needles compared with non-filtered needles of varying gauges?

Hypothesis

There is no significant difference in the number of glass particles obtained from drugs aspirated from glass ampules using 19-gauge filtered, 18-gauge non-filtered, 20-gauge non-filtered, or 25-gauge non-filtered needles.

Variables

Independent variables are: 1) the size of the needle, and 2) filtered or non-filtered needle. The dependent variable is the number of glass particles counted in solution after the glass ampules are opened.

Definition of Terms

The operative definitions used in this study are as follows:

Micrometer. The term micrometer is a unit of measurement of size. One micrometer equals one millionth of a meter, (abbreviated um).

Buccal. The term buccal refers to the cheek region.

Phlebitis. Phlebitis refers to inflammation of a vein with accompanying pain and tenderness.

Occlusion. An occlusion is an obstruction to the flow of blood through a vein or artery.

Embolus. An embolus refers to a clot, usually part or all of a thrombus, brought by the blood from another vessel and forced into a smaller one, resulting in obstructed circulation.

Thrombus. A thrombus is an aggregation of blood factors, primarily platelets and fibrin with entrapment of cellular elements, frequently causing vascular obstruction.

Granuloma. The term granuloma refers to a tumor-like mass of tissue due to a chronic inflammatory process associated with infectious disease or invasion by a foreign body.

Lipid. A lipid is a group of substances comprising fatty, greasy, oily, and waxy compounds that are insoluble in water.

Filter needle. A filter needle is a sterile needle containing a filter of specific pore size. The needle used in this study had a 5 micron pore size.

Non-Filter needle. A non-filter needle is a sterile needle that does not contain a filter.

Glass particle. A glass particle is a macroscopic and/or microscopic fragment of glass found in solution following the opening of glass ampules.

Assumptions

The assumptions made in this study are:

1. Filtered needles should be impermeable to glass particles.

2. The larger the needle gauge, the greater the number of glass particles present in the aspirated solution.

3. The researcher and assistant correctly record and document data.

Limitations

The limitations of this study are:

1. After ampules are opened, aspirated through a specific needle and viewed under a microscope, only glass particles are counted.

2. Glass ampules from different manufacturers, when broken, contain different numbers of glass particles.

3. The technique of aspiration varies from sample to sample.

4. The amount of sample placed on microscope slide varies.

5. Different medications with different lot numbers were examined.

6. Glass ampules from different companies were studied.

7. All glass contamination was contained in the 0.5 ml sample.

Delimitations

The delimitations of this study are:

1. The sample population was sufficiently large.

2. Needles were limited to 18-gauge non-filtered, 19-gauge filtered, 20-gauge non-filtered, and 25-gauge non-filtered.

3. Each ampule was opened in an identical way.

4. Each medication sample was aspirated from the ampule immediately after it was opened.

5. Each sample was identified in a way to prevent the researcher from being aware of what type or gauge of needle was used.

6. The same quantity of surface area was examined under the microscope.

Conceptual Framework

Many of the medications used during the operative period by anesthesia providers are contained in single-dose glass ampules. The top portion of the ampule is broken to allow access to the medication. A syringe with a needle attached is then used to aspirate the medication out of the ampule. The medication remains in the syringe until it is needed by the anesthesia provider. When needed, the medication is either injected directly through the needle into a special port in the patient's I.V. fluid tubing or the needle is removed and the syringe attached to a different port in the I.V. tubing. Regardless of the method, any glass fragments present in the medication are injected into the patient's vascular system.

To allow ease with opening, glass ampules are either transparent metal etched, transparent chemically etched, amber metal etched, or amber chemically etched at the top of neck (Sabon et al., 1989). Studies have demonstrated that regardless of the type of etching, glass fragments fall into the medication solution upon opening of the ampules (Sabon et al., 1989). These glass fragments can then be aspirated along with the medication through a needle attached to a syringe.

Needles come in varying length and diameter, or gauge, which are identified on the packages they are contained. This labeling allows the provider to choose the length and gauge of needle desired. The gauge identified is inverse to the needle size. For example, a 25-gauge needle has a smaller diameter than an 18-gauge needle.

Also available are needles that contain a filter inside the hollow tube. These needles contain filters of varying pore size that allow passage of glass particles no larger than the specified pore size to pass through the needle into the syringe when the medication is aspirated from the ampule.

Some I.V. tubing contains "in-line" filters designed to prevent glass particles from entering the patient's vascular system. However, this tubing type is not routinely used.

Summary

Many of the medications used during the operative period by anesthesia providers are contained in single-dose glass ampules. Studies have demonstrated that the opening of glass ampules causes glass particles to contaminate the medication. This medication is then aspirated through a needle on a syringe and subsequently injected into the patient I.V. Studies exist supporting the use of filtered needles to aspirate the medication from the ampule. Contradictory research also exists stating that filtered needles do not reduce particulate contamination.

Some medical facilities allow the anesthesia practitioner the option to use whatever needle he/she chooses, with both filtered and non-filtered needles of various gauges available. However, other facilities do not provide this option and either require the use of filtered needles or to the extreme not even have them available.

If filtered needles are shown to significantly reduce glass particle contamination in drugs obtained from glass ampules, then standardization of their use should be required in an effort to continuously provide safer patient care. If filtered needle use does not significantly reduce particulate contamination, then the necessity of their use, availability, and expense should be reevaluated.

Chapter Two

Review of Literature

Effects of Glass Particles on the Human Body

If a particle is introduced into a vein, it will travel to the right side of the heart via the systemic venous system. It will pass through the right atrium, to the right ventricle and then to the pulmonary artery. The pulmonary artery terminates in a massive capillary bed in the lung. Since these capillaries have a diameter of 7 to 12 microns, any particles of this size may become lodged. If this occlusion inhibits oxygenation or normal metabolic activity, cellu'ar damage or tissue death may result (Jonas, 1966).

Liebow (1949) and Hales (1956) have demonstrated that large arterio-venous (AV) shunts exist in the human lung. Particles entering the systemic circulation might bypass the pulmonary capillary bed and come to rest in some other organ of the body.

Turco (1974) discovered that phlebitis caused by microparticulates contained in I.V. fluids was a potentially fatal disorder. Falchuk et al. (1985) published a study demonstrating the effect of using I.V. in-line filters to decrease the incidence of microparticulate-induced phlebitis. Two hundred seventy seven patients received infusions through I.V. sets with 0.22-um-IVEX-HP filters, while 264 received infusions without filters. Each infusion was evaluated daily for a maximum of 3 days. The incidence of phlebitis on days 1, 2, and 3 of the study was 14.3%, 31.1% and 27% respectively for patients receiving infusions without filters and 6.8%, 9.7%, and 11.3% respectively for those receiving infusions through the filters. The incidence of phlebitis was reduced by approximately two-thirds where patients received infusions through the filters.

Brewer and Dunning (1947) published the results of a study which was based on the opinion that glass particles of any size, when injected intravenously, result in embolus formation. Rabbits were injected, via the ear vein, with varying quantities of different suspensions of glass particles. One group of animals received 32 days of injections with a total of 0.416 grams of glass per animal. Based on body weight, this is about 14 grams in a human in one month, or about 0.5 grams per day. Other animals were injected with lighter suspensions over longer time periods. When 1 ml of a 1.3% suspension of glass was injected for 32 days, no pneumonia or inflammation was noted. Venules were

dilated to capacity. Capillaries were moderately engorged. Grossly the animals appeared well. Macroscopically the organs appeared normal and the lungs had no gross pathology. In the animal that received injections for one year, small glass particles were found in the liver and intestine with giant cells found in the spleen and lungs. A second experiment (Brewer & Dunning, 1947) was conducted where 1,089 mice were injected intravenously with an injectate obtained from ampules in an attempt to produce fatal embolism. This was conducted over several months. In no case did either death occur or were latent effects noted. Brewer and Dunning concluded that occasional particle contamination of ampule preparations did not produce significant pathology and that massive doses were required to produce significant pathology.

Intravenous Fluids and Particles

Garvan and Gunner (1964) examined samples of I.V. fluids from several countries and found most contained particles of either rubber, cellulose fibers, fungal elements, crystals, or starch. They conducted experiments where rabbits received I.V. normal saline via the ear vein. Each rabbit received a different volume over a differing length of time. All rabbits remained healthy and without any side effects during the injections and the lungs appeared normal to the naked eye at autopsy. Histopathologically, capillary and arterial granulomas were found in the lungs. Each granuloma contained cellulose fragments. Further research by Garvan and Gunner

(1964) revealed similar findings in the lungs of patients who had received large volumes of intravenous fluids prior to their death. It was concluded that most brands of I.V. fluids contain particles that are potentially harmful to patients' lungs.

Decreased Particles With Use of In-line Filters

Davis, Turco, and Sivelly (1970) published a report demonstrating that I.V. fluids from different manufacturers contained variable amounts of particulate matter. The addition of infusion administration sets or additives such as vitamins or potassium chloride (KCl) increased the number of particles. Use of an in-line filter reduced the number of particles present.

Davis and Turco (1971) and Turco and Davis (1972, 1973a, 1973b) published subsequent papers demonstrating that I.V. fluid manufacturers were reducing the number of particles contained in their fluids. Use of in-line filtration to further decrease particulate contamination was supported.

Wall and George (1986) published a letter stating that some of the particulate contamination found in I.V. infusions was due to the opening of glass ampules, breaking of container seals, and insertion of syringes or needles during transfer of the additive to the infusion. The use of in-line filters with pore sizes varying between 0.2 and 0.5 um may reduce the amount of particulate contamination. Wall and George (1986) did state "that the potential benefits of in-line filters must

be weighed against their possible disadvantages. They cost more, they restrict the flow of colloid solutions and lipid suspensions and they add a potential site for disconnection."

Glass Ampules, Glass Particles Contamination and Use of Luer Lock Openings

Kempen, Sulkowski, and Sawyer (1989) convinced of glass particle contamination occurring with the process of opening glass ampules sought to prove drug contamination via external ampule surface particles from 1-ml ampules. A 1% methylene blue solution was applied to the neck of ten 1-ml ampules of epinephrine in two coats and allowed to dry. Other ampules of the same lot of epinephrine were not painted with methylene blue to serve as a control. A spectrophotometer was calibrated at 660-nm wavelength to provide methylene blue with maximum light absorption. Each ampule was then opened in a standard fashion and the contents placed into the spectrophotometer where the solutions were measured for 1 minute. Six of the treated samples were contaminated with methylene blue whereas no significant light absorption occurred in the untreated samples. The incidence of contamination was found to be statistically significant ($p < .01$). In two of the treated samples, frank glass fragments were seen floating in the solution. Kempen et al. (1989) stated that "ampules are often carried in pockets (narcotics in anesthesia practice), intimately handled, stored on dusty shelves, and not generally disinfected before

opening." They recommended that glass ampules be eliminated with introduction of vials with Luer lock openings and that if glass ampules are used, disinfection of ampule necks prior to opening would be beneficial.

External Surface Particles and Luer Lock Openings

Kempen and Treiber (1990) conducted a similar experiment examining the incidence of drug contamination with particles from the external surface of glass ampules. Methylene blue solution was again applied to the neck of glass ampules and the solutions were read for wavelength absorption via a spectrophotometer. Contamination occurred in 66% of the samples. Recommendations for the use of Luer-lock openings on drug containers and glass ampule disinfection were made.

External Contamination of Glass Ampules

Zacker, Zornow, and Evans (1991) published a study motivated by reports of postoperative sepsis due to I.V. injection of contaminated solutions of propofol (Diprivan®). Zacker et al. (1991) sought to determine if bacterial contamination of glass ampule contents could be minimized by cleaning the neck of the ampule with alcohol prior to opening. Glass ampules of 1% propofol and 1% lidocaine were swabbed with a solution of Staphylococcus epidermidis. Half of these ampules were then wiped with alcohol prior to opening. A sample from each ampule was obtained and placed into a nutrient broth for overnight incubation at 37°C. These

solutions were then plated on agar, reincubated at 37°C overnight, then examined for bacterial growth. Three of eight lidocaine ampules and six of eight propofol ampules not cleaned with alcohol demonstrated bacterial growth. All ampules cleaned with alcohol before opening remained sterile. This data demonstrated that bacterial contamination could occur upon opening glass ampules and that use of alcohol to clean ampules prior to opening could reduce the risk.

Fine Bore Needles and Filters

Katz et al. (1973) recommended the use of fine-bore needles or filters when withdrawing solutions from glass ampules to avoid injecting glass particles into patients. Katz et al. (1973) stated "it is unlikely that fragments aspirated through a fine needle would cause harm, but there have been reports of pulmonary microemboli, thrombi, and granulomas resulting from small-particle contamination of large-volume injections."

Furgang (1974) noted glass particles in single-dose glass ampules of lidocaine with a "shower of minute particles falling into the solution upon opening the ampule." He conducted a study where glass ampules, opened as in clinical practice, demonstrated visible glass particles at the bottom of each ampule. Each solution was aspirated almost to completion, the last drop removed with a 22-gauge spinal needle, and examined microscopically. Each ampule contained 5 to 10 particles 20 to 100 microns long. Numerous smaller

particles were also noted. Furgang (1974) recommended that in-line filters be used, that the aspirating needle not be placed in the bottom of the ampule, and that solutions not be completely withdrawn.

Ampules Versus Vials, Glass Versus Plastic Syringes and Use of Filters

Eriksen (1988) published a multipurpose study conducted to evaluate and to quantitate the amount of particulate contamination in various solutions of 0.5% bupivacaine obtained from either glass ampules or vials, use of glass versus plastic syringes, and if bacterial filters reduced particulate contamination. One hundred and eighty preparations were produced from commercially prepared glass ampules of 0.5% bupivacaine. Sixty preparations were produced using distilled water as a control. Various combinations of syringe, method of dispensing solution and filter/non-filter usage were evaluated. After aspirating the solutions into the appropriate syringes, the solutions were passed through a filter, then examined microscopically with deposits classified according to their greatest length into groups less than 50 um, 50-200 um, and greater than 200 um. Results demonstrated no difference in type of syringe used (glass or disposable plastic) or whether a glass ampule, open vial, or perforated vial was used. It was demonstrated that cotton-like foreign body material appeared in the filtered groups, which caused an

increase in the amount of particulate contamination detected. However, no glass fragments were found in the filtered groups.

Opening Ampules by Hand Versus Commercial Opener

Giambrone (1991) conducted a study comparing the amount of glass fragmentation following opening of glass ampules by hand versus use of a commercial opener. Twenty, 2-ml transparent, chemically etched, single dose glass ampules were divided into groups of 10. Group 1 was opened by hand while Group 2 was opened using a commercially available plastic ampule opener. The sterile water contents of all ampules were aspirated using separate 18-gauge non-filtered needles, then placed into a Buchner funnel and filtered. While still damp, the filters were immediately examined under a light microscope fitted with an ocular micrometer. The number and size of glass particles were analyzed by analysis of variance (ANOVA) for repeated measures. No significant difference between the two methods of ampule opening or the size of glass particles was found.

Immediate Versus Delayed Aspiration

Turco and Davis (1972) investigated the effect that two different methods of medication withdrawal had on glass particle contamination. In one method, all ampules were opened then drawn into the syringe. In the other method, one ampule at a time was opened and the contents then aspirated. Particles from the samples were then counted using the Millipore AR-2 technique. Also investigated was the effect of

using a sterile Millex filter during aspiration from glass ampules. Results revealed that the least number of particles were found when using the Millex filter while the greatest number of particles were found in the samples where all the ampules were opened and then aspirated. Immediate aspiration following ampule opening fell between the two.

Different Needle Gauges and Use of Filters

Shaw and Lyall (1985) published a study where 5-ml ampules of water were opened by hand and the contents aspirated with a sterile 50-ml syringe and infused through a 20-um Millipore filter. The filter was then examined microscopically for the presence of glass particles. This process was repeated using syringes with 19- and 21-gauge needles attached. In all of the ampules used, glass particles could be seen microscopically floating in the ampule following opening. All millipore filters had glass particles on them. Free particles of glass were aspirated through the 19 gauge but not through the 21 gauge needle. It was concluded that filters should be used when drawing samples from glass ampules.

Ampule Size and Particle Contamination. Effect of Different Needle Sizes

Carbone-Traber and Shanks (1986) conducted a study whose purpose was twofold - part one determined the effect of ampule size on the amount of glass particle contamination; part two compared glass particle contamination after aspiration of

ampule contents through various size needles with and without filters attached. In part one, 1-, 5-, and 20-ml single-dose, glass ampules were opened by hand; the contents of each aspirated through a 3-mm internal diameter tubing attached to a prewashed syringe. The contents were then filtered through a 0.22 micron, 47-mm filter in a Buchner funnel attached to a vacuum. The wet filters were then examined microscopically and the total number of glass particles counted. Results demonstrated that the number of glass particles counted was proportional to the size of the glass ampule used. The 1-ml ampules had significantly less particles then did the 5- and 20-ml ampules.

In part two, 40, 5-ml glass ampules were randomly assigned to one of four groups based on methods of aspiration. Group 1 used 3-mm plastic tubing (control); Group 2, 18-gauge, 3.8-cm needle; Group 3, 25-gauge, 1.6-cm needle; Group 4, 5-micron, 19-gauge, 2.5-cm Millipore filter needle. All ampules were opened by hand, the contents aspirated into a 10-ml prewashed syringe using the needle or tubing accordingly assigned. Once aspirated, the contents of each syringe were filtered and counted using a light microscope. Group comparisons of particle numbers were made by ANOVA, followed by a Neuman-Kuel test. A $p < .05$ was considered statistically significant. Results revealed no significant difference in the numbers of particles aspirated by any method. It was also discovered that glass particles were able to penetrate through the filters during the force of aspiration. This study concluded

that neither the use of filters or small gauge needles provides any significant reduction in glass particle contamination.

Sabon et al. (1989) conducted a study whose purpose was two fold: 1) to quantitate the number and size of glass particles aspirated from glass ampules after opening, and 2) to determine if different aspiration methods could influence the amount of glass particles aspirated. In part one of the study, 80, 10-ml, single-dose glass ampules were randomized into four groups of 20 ampules. Group 1, control group, was aspirated through 7-cm length, 3-mm plastic tubing; Group 2 was aspirated through an 18-gauge, 3.8-cm needle; Group 3 was aspirated through a 19-gauge, 5-um filtered, 3.8-cm needle; and Group 4 was aspirated through a 0.22 um in-line filter. All ampules were opened by hand with the contents aspirated into a prewashed 10-ml syringe. The contents of the syringe were then emptied into a Buchner funnel and filtered through a 0.45-um, 25-mm nylon filter attached to a vacuum flask. The wet filter was examined under a light microscope at 10x power using a calibrated ocular micrometer. Results were analyzed by one-way ANOVA. Results indicated the mean number of particles in Group 1 was 100.6 $\pm$16.3 with particle size ranging from 10 to 1,000-um. Group 2 results revealed the mean number of particles as 65.6 $\pm$18.7 with maximum particle size less than 400-um. Group 3 results indicated a decrease in the mean particle number to 1.3 $\pm$0.3. Group 4 results

revealed a mean of 1.2 ±0.3. These decreases were significantly different ($p < .01$).

Particle Contamination Based on Color and Method of Ampule Scoring

In Part 2, (Sabon et al., 1989), 80, 10-ml, single-dose glass ampules were again divided into four groups of 20 ampules based upon their color and method of scoring: Group 1, transparent, metal-etched; Group 2, transparent, chemical scored; Group 3, amber, metal-etched; Group 4, amber, chemical scored. All ampules were opened by hand and aspirated through an 18-gauge needle into a prewashed 10-ml syringe and filtered as in Part 1. Results were analyzed by two-way ANOVA. Results demonstrated that the mean number of particles found in each transparent, metal-etched ampule was 45.9 ±15.4. This value was significantly greater ($p < .01$) than the other three ampule types. Transparent, chemically scored was 3.2 ±0.9. Amber, chemically scored was 3.1 ±0.6. Amber, metal-etched had 6.0 ±1.7 particles.

It was concluded that single-dose glass ampules, once opened, contain glass particles in solution. Transparent metal-etched ampules were noted to contain the most glass particles. Filtration was determined to be an effective means of decreasing particle contamination.

Summary

If a foreign body such as a glass particle is introduced into the systemic venous system, it can cause an occlusion inhibiting oxygenation resulting in cellular damage or tissue death. In anesthesia practice, when glass ampules are opened, a shower of glass particles are introduced into the ampule contents which are then aspirated and ultimately injected into the patient.

Several investigators have reported that the use of small gauge needles, filtered needles, or in-line filters reduce glass particle number. There are also conflicting reports demonstrating that particle number is unaffected by use of small gauge needles, filtered needles, or in-line filters. Review of the literature, therefore, suggests conflicting results with the use of filters of any kind or small gauge needles.

Chapter Three

Methodology

Purpose statement

There is contradictory information pertaining to whether the use of filtered needles reduces or eliminates the number of glass particles aspirated and consequently administered to patient's following aspiration of medications from glass ampules. The purpose of this study was to determine if the use of filtered needles, when compared with non-filtered needles of varying gauges, significantly reduced the number of glass particles obtained from medications aspirated from glass ampules. The type and size of needle used for this study (18-gauge non-filtered, 19-gauge filtered, 20-gauge non-filtered, and 25-gauge non-filtered) are most commonly used at the medical facility this study was conducted.

Design

A quasi-experimental design was used because of the manipulation of independent variables: the size of needles used and whether filtered versus non-filtered needles were used. There was randomization of needles into four groups: Group A, Group B, Group C, and Group D. There was no control group used.

Setting and Sample

A large, mid-Atlantic university hospital was the setting for this research project. The sample consisted of 100 needles total, 21 of 18-gauge non-filtered, 29 of 19-gauge filtered, 24 of 20-gauge non-filtered, and 26 of 25-gauge non-filtered needles. The sample also consisted of 100, 2-ml glass ampules.

Procedure

The following items were obtained for the study: 100, 10-milliliter (ml), sterile, plastic syringes; 21, 18-gauge, non-filtered, sterile needles; 29, 19-gauge, filtered, sterile needles; 24, 20-gauge, non-filtered, sterile needles; 26, 25-gauge, non-filtered, sterile needles; 100, 2-ml, sterile, single-dose glass ampules; glass microscope slides; glass microscope slide cover slips; and a microscope with 10X magnification.

An assistant was responsible for needle selection, ampule breakage, and aspiration of ampule contents. This was to ensure validity of testing by the researcher.

The needles were placed into a container which was shaken to aid in the randomness of selection. The assistant obtained a needle from the container and attached the needle to a syringe. Each of the syringes was numbered sequentially from 1 to 100. All of the glass ampules were opened identically. The assistant was an anesthesia provider and therefore familiar in the methodology of glass ampule opening and medication aspiration. The ampules were held in one hand, while the neck of the ampule was broken with the use of the thumb and index finger of the other hand. An unopened alcohol pledget was wrapped around the neck of the ampule prior to opening to protect the assistant's fingers from lacerations from glass fragments.

The contents of the entire ampule were then aspirated into the syringe through the selected needle as is common in anesthesia practice. The needle was removed from the syringe, discarded, and a plastic, screw-top was placed on the syringe where the needle had been to secure the contents within.

The researcher took the syringe, inverted it several times to ensure mixing of the contents, removed the screw-top and discarded 1.5 ml of the syringe contents into a waste container, leaving approximately 0.5-ml of sample for examination. The sample was placed on a glass microscope slide, covered with a glass cover slip and examined using a

light microscope with 10X power magnification. Each slide was examined throughout the entire cover-slipped area, scanning from top-left corner to bottom-right corner, going horizontally left-to-right, right-to-left. All particles seen were counted using a hand held counting device.

The assistant maintained a log of sample number, needle size used, medication contained in the ampule, lot number of the medication. The researched kept a separate log that contained sample number and number of particles counted.

Instrumentation

One hundred, 2-ml, glass ampules and 100, 10-ml, syringes were required for this study. Twenty five each of the following needle types: 18-gauge non-filtered, 19-gauge filtered, 20-gauge non-filtered, and 25-gauge non-filtered. One hundred glass microscope slides with cover slips were used for sample analysis. Samples were examined and counted using a microscope with 10x power magnification.

Data Analysis

The researcher compared the results of all four groups to one another by analysis of variance (ANOVA). A p-value of .05 was pre-established as statistically significant.

Chapter Four

Results

The sample population consisted of 100 needles used for aspirating and injecting drugs during the operative period. The 100 needles were randomly allocated into four groups: Group A, 18-gauge, non-filtered (n = 21); Group B, 19-gauge, filtered (n = 29); Group C, 20-gauge, non-filtered (n = 24); Group D, 25-gauge, non-filtered (n = 26). Data collection proceeded according to the protocol in the methodology section.

A wide variance in the number of particles counted with each needle was noted. Group A (18-gauge, non-filtered needles) had a particle number range counted from 36 to 711 particles. Group B (19-gauge, filtered needles) had a particle number range of 30 to 951 particles. Group C (20-gauge, non-filtered needles) had a particle number range of 132 to 691 particles. Group D (25-gauge, non-filtered needles) had a particle number range of 56 to 881 particles.

Table 1 summarizes the mean number of particles counted in each group with standard deviations. The mean number of particles counted in each group demonstrates that Group D (25-gauge, non-filtered needles) allowed the greatest number of glass particle contamination followed by Group A (18-gauge, non-filtered needles); Group C (20-gauge, non-filtered needles); and Group B (19-gauge, filtered needles).

Table 1

Number of Particles Counted by Needle Size

	Needle Size (Gauge)			
# Particles	18 (NF)	19 (F)	20 (NF)	25 (NF)
Mean	271.238	267.793	270.542	279.769
S.D.	148.398	231.493	156.894	185.018

Note. NF = Non-filtered; F = Filtered; S.D. = Standard Deviation

The number of glass particles counted following aspiration through each needle was analyzed using analysis of variance (ANOVA) to test whether there was no significant difference in the number of glass particles counted following aspiration

through 18-gauge, non-filtered; 19-gauge, filtered; 20-gauge, non-filtered; and 25-gauge, non-filtered needles (H_o: $u_A = u_B = u_C = u_D$). ANOVA demonstrated that there was no significant difference ($p > .05$) in the number of glass particles counted in each group.

Chapter Five

Discussion

Purpose of the Study

The objective of the study was to determine if there was a significant reduction in the number of glass particles obtained from I.V. fluids in glass ampules when using 19-gauge filtered needles compared with 18-gauge non-filtered, 20-gauge non-filtered, and 25-gauge non-filtered needles. The hypothesis for this study stated that there was no significant difference in the number of glass particles obtained from drugs in glass ampules using 19-gauge filtered needles compared to the three varying gauge non-filtered needles. The results of the study failed to reject this hypothesis.

Correlation with Previous Studies

Numerous studies have demonstrated that glass particle contamination occurs following the breaking of glass ampules. Furgang (1974) performed a study that demonstrated visible

glass particles in solution following the opening of glass ampules. Shaw and Lyall (1985) conducted a study where glass ampules were opened by hand, contents aspirated with a 50-ml syringe and infused through a 20-um filter. The filter was examined microscopically for the presence of glass particles. Wall and George (1986) stated that some particulate contamination found in I.V. infusions was due to the opening of glass ampules. Ericksen (1988) evaluated and quantitated the amount of particulate contamination in various solutions of 0.5% bupivacaine contained in glass ampules. The current study demonstrated glass particle contamination following the opening of 2-ml glass ampules.

Some studies have demonstrated contradictory results with the use of varying sized needles and glass particle contamination. Shaw and Lyall (1985) opened glass ampules by hand, aspirated the contents with a 50-ml syringe then infused through a 20-um filter. This process was repeated with 19-gauge and 21-gauge needles. Filters were examined microscopically and all had glass particles on them. Free glass particles were aspirated through the 19-gauge but not through the 21-gauge needle. Carbone et al. (1986) randomly assigned 5-ml glass ampules into four groups based on aspiration methods. The results revealed no significant difference in particle numbers. Sabon et al. (1989) conducted a study comparing aspiration methods, as well as, needle gauges. Results showed particle number decreased as needle gauge decreased. The current study demonstrated no

significant difference in particle number regardless of needle gauge.

Finally, numerous studies have demonstrated contradictory results that use of in-line filters or filtered needles reduces glass particle contamination. Turco and Davis (1972) demonstrated that using a sterile filter reduced the number of glass particles obtained after opening glass ampules. Katz et al. (1973) recommended use of filters when withdrawing solutions from glass ampules. Furgang (1974) recommended use of in-line filters. Shaw and Lyall (1985) concluded that filters should be used to obtain samples from glass ampules. Wall and George (1986) stated that use of in-line filters may reduce glass particulate contamination. Carbone-Traber and Shanks (1986) when comparing glass particles aspirated through 3-mm plastic tubing; 18-gauge, 3.8-cm needles; 25-gauge, 1.6-cm needles; and 5-micron,19-gauge, 2.5-cm millipore filtered needles, had results revealing no significant difference in particle numbers, including with the use of filters. Ericksen (1988) evaluated glass particulate contamination in solutions of 0.5% bupivacaine and noted no glass fragments with use of filters. Sabon et al. (1989) compared glass particle contamination following aspiration through 7-cm length, 3-mm plastic tubing; 18-gauge, 3.8-cm needles; 19-gauge, 5-um filter, 3.8-cm needles; and 0.22-um in-line filter. Results demonstrated that particle number decreased as needle gauge decreased with the smallest number of particles aspirated through the in-line filter. The

current study demonstrated no significant reduction in glass particle contamination with use of a 19-gauge filtered needle.

Limitations

Two alternatives were examined to determine which methodology to use to count the number of glass particles present in a sample of medication contained in glass ampules following aspiration through various needles (18-gauge non-filtered, 19-gauge filtered, 20-gauge non-filtered, and 25-gauge non-filtered). First an attempt was made to take the sample aspirated from the glass ampule, pass it through filter paper and then examine the filter paper under a light microscope to count the observed particles. This method proved unsuccessful in that only filter fibers could be seen due to their denseness. Second, a glass ampule was broken, the contents aspirated into a syringe which was inverted, the contents of which were then placed on a microscope slide and examined under a light microscope. This method clearly demonstrated the presence of glass particles and was thus chosen as the method for the study. However, this method ultimately proved not to be precise enough as seen by the wide variation in the number of glass particles counted and the standard deviations derived. Weighing of filter paper might be an alternative to counting glass particles. Samples could be obtained following the format of this study, then dispensed onto filter paper which would then be weighed. It might be

hypothesized that the greater the number of glass particles present, the heavier the filter paper.

Difficulty in obtaining a sufficient number of glass ampules caused another limitation. There was a lack of standardization of glass ampules used. Glass ampules of different lot numbers, different colors and method of scoring, different manufacturers, and containing different drugs were used. A smaller sample size might allow for increased standardization of glass ampules.

The final limitation was an error in obtaining an accurate number of each of the specified needle type and gauge. In this study, 25 of each needle type and gauge was not used, as was intended. The reason for this error is uncertain, but possibly due to either an inaccurate count of each type of needle before being placed in the container for randomization or a clerical error made by the research assistant during documentation of needle type prior to sample analysis.

Difficulties

The primary difficulty of this study was the time involved counting the glass particles using a microscope and the lack of certainty that only glass particles were being counted. The study was easy to accomplish and few difficulties were encountered.

Recommendations for Future Studies

The following list contains recommendations for further research:

1. Since it is mandatory to find a more precise method of measurement, replicating the study using filter paper to compare it's weight prior to and following drying of drugs that have been aspirated from glass ampules using filtered and non-filtered needles of varying gauges. This would eliminate the potential of counting anything but glass particles under the microscope.

2. Some of the studies utilized a Buchner funnel to aspirate the sample through before examination under the microscope. Use of a Buchner funnel would allow for a more accurate comparison with these studies.

3. Replicating the study using ampules of the same drug, lot number, manufacturer, and method of scoring would decrease the number of extraneous variables.

4. Use all of the aspirated drug solution contained in the glass ampule instead of discarding all but 0.5 ml.

Conclusions

In summary, the results of the current study revealed no statistical difference in the number of glass particles obtained from drugs contained in glass ampules following ampule opening and aspiration through 18-gauge, non-filtered; 19-gauge, filtered; 20-gauge, non-filtered; and 25-gauge, non-filtered needles. The p-value was not less than .05;

therefore, this researcher failed to demonstrate a difference in the number of glass particles obtained between the four groups. Previous studies indicated that use of either filters, filtered needles, or smaller gauge needles were significantly effective in reducing the number of glass particles obtained. This study failed to concur with these findings. The method of counting glass particles proved to be inaccurate and imprecise. No significant difference in the mean number of glass particles counted following aspiration through 18-gauge, non-filtered; 19-gauge, filtered; 20-gauge, non-filtered; and 25-gauge, non-filtered needles was noted. However, each needle type/size had a wide variation in the number of glass particles counted to obtain the mean. Each standard deviation was almost equal to the mean for that specific needle. Thus, the results obtained were neither accurate nor reliable using this method of determining the amount of glass particle contamination and, therefore, is not an accurate comparison to results obtained in other studies.

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Appendix A

Data Collection Form

Appendix A

Data Collection Form

SAMP #	DRUG	MANUFACTURER	LOT #	NDL GAUGE

Appendix B

Result Log Form

Appendix B

Result Log Form

SAMPLE #	NUMBER OF PARTICLES

Vita

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